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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and ASTRAZENECA UK LIMITED, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Limited (collectively, "Plaintiffs"), by their attorneys, bring this complaint against Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively, "Defendants"), and hereby allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(a-c, e). This action relates to an Abbreviated New Drug Application ("ANDA") No. 213298 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' DALIRESP® pharmaceutical products that are sold in the United States.

The Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

3. Plaintiff AstraZeneca AB is a public, limited-liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. Plaintiff AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA.

5. Plaintiffs AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited (collectively, "Plaintiffs" or "AstraZeneca") are all wholly-owned subsidiaries of AstraZeneca PLC.

6. On information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having its principal place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad, India.

7. On information and belief, Defendant Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

8. On information and belief, Aurobindo Pharma Limited is in the business of manufacturing and supplying pharmaceutical drugs to Aurobindo Pharma USA Inc.

9. On information and belief, Aurobindo Pharma USA Inc. is in the business of marketing, distributing, and selling, in the State of New Jersey and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Aurobindo Pharma Limited.

10. On information and belief, Aurobindo Pharma USA Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited.

Jurisdiction and Venue

11. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 8,536,206 ("the '206 Patent"), U.S. Patent No. 8,604,064 ("the '064 Patent"), and U.S. Patent No. 8,618,142 ("the '142 Patent) (collectively, "the asserted patents").

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

13. On information and belief, this Court has personal jurisdiction over Defendants because Aurobindo Pharma USA Inc. is a corporation with a principal place of business in New Jersey. On information and belief, Aurobindo Pharma USA Inc. is acting as the agent of Aurobindo Pharma Limited with respect to ANDA No. 213298.

14. This Court also has personal jurisdiction over Defendants because, *inter alia*, on information and belief, Defendants have continuous and systematic contacts with the State of New Jersey as they regularly conduct business in the State of New Jersey, either directly or through one or more agents and/or subsidiaries, has purposefully availed themselves of the privilege of doing business in the State of New Jersey, and intend to market, offer to sell, sell, or distribute Aurobindo Pharma Limited's Infringing ANDA Product in the State of New Jersey upon approval of ANDA No. 213298.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400 as to Aurobindo Pharma USA Inc. because, on information and belief, Aurobindo Pharma USA Inc. has a principal place of business in New Jersey.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c)(3) as to Aurobindo Pharma Limited because, on information and belief, Aurobindo Pharma Limited is an Indian corporation and not resident in the United States.

Regulatory Requirements for New and Generic Drugs

17. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

18. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

19. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

20. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Approved Drug Product

21. AstraZeneca Pharmaceuticals LP is the current holder of NDA No. 022522, for DALIRESP®, Roflumilast Tablet 500 mcg, which was first approved by FDA on February 28, 2011. Plaintiffs market the approved drug product under the tradename DALIRESP®. DALIRESP® is approved as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. A copy of the complete prescribing information for DALIRESP® approved in NDA No. 022522 is attached as **Exhibit A**.

22. FDA has listed the '206, '064, and '142 Patents in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 022522.

23. AstraZeneca Pharmaceuticals LP maintains the listing of the '206, '064, and '142 Patents in the Orange Book.

24. AstraZeneca AB is the current owner by assignment of the '206, '064, and '142 Patents.

25. On April 29, 2016, AstraZeneca AB received ownership of the NDA No. 022522 from Forest Pharmaceuticals, Inc. and Forest Research Institute Inc.

26. AstraZeneca UK Limited is the exclusive licensee of the '206, '064, and '142 Patents.

ANDA No. 213298

27. Upon information and belief, on or before March 13, 2019, Defendants submitted to FDA ANDA No. 213298 with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 500 mcg roflumilast tablets purportedly bioequivalent to DALIRESP®. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic DALIRESP® product.

28. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 213298 for the generic DALIRESP® product is a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation, *i.e.*, the same indication as that set forth in the approved labeling for DALIRESP®.

29. Upon information and belief, Defendants sent AstraZeneca Pharmaceuticals LP and AstraZeneca AB a letter dated April 5, 2019 (the "Notice Letter"). The Notice Letter represented that Aurobindo Pharma Limited had submitted to FDA ANDA No. 213298 with paragraph IV certifications for the '206, '064, and '142 Patents.

30. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of DALIRESP® before the expiration of

the patents listed in the Orange Book for NDA No. 022522. Hence, Defendants' purpose in submitting ANDA No. 213298 is to market products described therein before expiration of the'206, '064, and '142 Patents.

Count 1: Patent Infringement of the '206 Patent

31. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 30 above.

32. The '206 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on September 17, 2013. Plaintiff AstraZeneca AB is the owner of the '206 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '206 Patent. A true and complete copy of the '206 Patent is attached hereto as **Exhibit B**.

33. Upon information and belief, Defendants submitted ANDA No. 213298 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP® before the expiration of the '206 Patent.

34. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '206 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

35. Upon information and belief, if approved, the generic DALIRESP® product for which approval is sought in Defendants' ANDA No. 213298 will be administered to human patients as treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '206 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and

encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that they are in contravention of Plaintiffs' rights under the '206 Patent.

36. Defendants' manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic DALIRESP® product for which approval is sought in ANDA No. 213298 would actively induce and contribute to infringement of the '206 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

37. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '206 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of DALIRESP®.

38. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '206 Patent, alleging that the claims of the '206 Patent are invalid and that certain claims would not be infringed by Defendants' generic version of DALIRESP®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to DALIRESP® prior to the expiration of the '206 Patent.

39. Defendants have infringed the '206 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 213298 with a Paragraph IV certification and seeking FDA approval of ANDA No. 213298 to market a generic version of DALIRESP® prior to the expiration of the '206 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of DALIRESP®, or induce or contribute to such conduct, they would further infringe the '206 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '206 Patent. Plaintiffs do not have an adequate remedy at law.

Count 2: Patent Infringement of the '064 Patent

42. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 41 above.

43. The '064 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on December 10, 2013. Plaintiff AstraZeneca AB is the owner of the '064 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '064 Patent. A true and complete copy of the '064 Patent is attached hereto as **Exhibit C**.

44. Upon information and belief, Defendants submitted ANDA No. 213298 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP® before the expiration of the '064 Patent.

45. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '064 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon information and belief, if approved, the generic DALIRESP® product for which approval is sought in Defendants' ANDA No. 213298 will be administered to human patients as treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '064 Patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and

encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that they are in contravention of Plaintiffs' rights under the '064 Patent.

47. Defendants' manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic DALIRESP® product for which approval is sought in ANDA No. 213298 would actively induce and contribute to infringement of the '064 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

48. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '064 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of DALIRESP®.

49. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '064 Patent, alleging that the claims of the '064 Patent are invalid and that certain claims would not be infringed by Defendants' generic version of DALIRESP®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to DALIRESP® prior to the expiration of the '064 Patent.

50. Defendants have infringed the '064 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 213298 with a Paragraph IV certification and seeking FDA approval of ANDA No. 213298 to market a generic version of DALIRESP® prior to the expiration of the '064 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of DALIRESP®, or induce or contribute to such conduct, they would further infringe the '064 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

51. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

52. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '064 Patent. Plaintiffs do not have an adequate remedy at law.

Count 3: Patent Infringement of the '142 Patent

53. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 52 above.

54. The '142 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013. Plaintiff AstraZeneca AB is the owner of the '142 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '142 Patent. A true and complete copy of the '142 Patent is attached hereto as **Exhibit D**.

55. Upon information and belief, Defendants submitted ANDA No. 213298 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP® before the expiration of the '142 Patent.

56. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '142 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

57. Upon information and belief, as part of the ANDA filing, Defendants purportedly provided written certification to FDA that the claims of the '142 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of DALIRESP®.

58. Defendants gave written notice of their certification of invalidity and/or non-infringement of the '142 Patent, alleging that the claims of the '142 Patent are invalid and that certain claims would not be infringed by Defendants' generic version of DALIRESP®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture,

use, and sale of a product bioequivalent to DALIRESP® prior to the expiration of the '142 Patent.

59. Defendants have infringed the '142 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 213298 with a Paragraph IV certification and seeking FDA approval of ANDA No. 213298 to market a generic version of DALIRESP® prior to the expiration of the '142 Patent. Moreover, if Defendants commercially use, offer for sale, or sell their generic version of DALIRESP®, or induce or contribute to such conduct, they would further infringe the '142 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

60. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

61. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '142 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendants have infringed the '206, '064, and '142 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 213298 is not earlier than the expiration date of the '206, '064, and '142 Patents, or any later expiration of exclusivity for the '206, '064, and '142 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates and those persons in active

concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '206, '064, and '142 Patent, including the product described in ANDA No. 213298;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 213298 would constitute infringement of the '206, '064, and '142 Patents, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

May 15, 2019

Respectfully submitted,

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NOTICE OF OTHER ACTIONS PURSUANT TO L.CIV.R. 11.2

I hereby certify that the following captioned actions are related to the matter in controversy because the matter in controversy involves United States Patent Nos. 8,536,206, 8,604,064, and 8,618,142 and the same drug product:

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, AND ASTRAZENECA UK LIMITED V. ALKEM LABORATORIES LTD., C.A. NO. 18-cv-16399 (D.N.J).

The undersigned hereby further certifies that the patents-at-issue were the subject of the previous Hatch-Waxman cases before this court, all of which have settled[1]:

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. TORRENT PHARMA INC. AND TORRENT PHARMACEUTICALS LTD., C.A. NO. 16-cv-02091 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. MICRO LABS USA, INC. AND MICRO LABS LTD., C.A. NO. 15-cv-03376 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. STRIDES PHARMA, INC. AND STRIDES PHARMA GLOBAL PTE LIMITED, C.A. NO. 15-cv-03378 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. APOTEX CORP. AND APOTEX INC., C.A. NO. 15-cv-03379 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. PRINSTON PHARMACEUTICAL INC., C.A. NO. 15-cv-03380 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. BRECKENRIDGE PHARMACEUTICAL INC., C.A. NO. 15-cv-03382 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. CITRON PHARMA LLC AND MSN LABORATORIES PRIVATE LIMITED, C.A. NO. 15-cv-03383 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. MYLAN PHARMACEUTICALS INC., C.A. NO. 15-cv-03384 (D.N.J);

[1] The following cases were consolidated into *In re Certain Consolidated Roflumilast Cases*, C.A. No. 15-03375 (D.N.J).

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. HETERO USA INC., HETERO LABS LIMITED UNIT-III, AND HETERO LABS LIMITED, C.A. NO. 16-cv-03385 (D.N.J);

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED V. ZYDUS PHARMACEUTICALS (USA) INC., C.A. NO. 15-CV-03377 (D.N.J.).

Dated: May 15, 2019

Respectfully submitted,

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